S1. Overview of the study based on the SPIRIT 2013 checklist.

Section	**SPIRIT item number**	**Item description**	**Study description**	**Page number where item can be found.**
Title	1	Title	An evidence-based digital support during one year after an Interdisciplinary Pain Rehabilitation Program for persons with chronic musculoskeletal pain to facilitate a sustainable return to work: study protocol for a registry-based multicentre randomized controlled trial.	Page 1, manuscript file
Trial registration	2a	Trial identifier and registry name	ClinicalTrials.gov registration number NCT05058547	Page 4, manuscript file
	2b	All items from the World Health Organization trial registration data set	Supplementary table S2.	Supplementary file S2
Protocol version	3	Date and version identifier	Version 1. 27 September 2021. NCT05058547	Page 4, manuscript file
Funding	4	Sources and types	The Swedish Research Council for Health, Working Life and Welfare: Dnr 2019-01264. Financial.	Page 19, manuscript file
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Christina Turesson[1], Gunilla Liedberg[1], Linda Vixner[2], Monica Löfgren[3], Mathilda Björk[4.] MB and GL formed the original research concept. CT, MB and GL contributed to the study design and CT will coordinate the project in cooperation with MB and GL. CT, ML and LV will be responsible for the unit coordinators at each participating unit and the inclusion of participants. All authors will collect and manage data during the trial. CT, MB and GL have written and revised this protocol with critical input from ML and LV. All authors have contributed important intellectual content to the manuscript. **Affiliations:**	Page 1 and 19, manuscript file

			1. Division of Prevention, Rehabilitation and Community Medicine, Department of Health, Medicine and Caring Sciences, Linköping University, Linköping, Sweden 2. School of Health and Welfare, Dalarna University, Falun, Sweden 3. Karolinska Institutet, Department of Clinical Sciences and Department of Rehabilitation Medicine Danderyd Hospital, 182 88 Stockholm 4. Pain and Rehabilitation Centre, Department of Health, Medicine and Caring Sciences, Linköping University, Linköping, Sweden	
	5b	Name and contact information for the trial sponsor	Linköping University 581 83 Linköping Sweden +46 28 10 00	Page 1, manuscript file
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	N/A	
	5d	Composition, roles, and responsibilities of the coordinating center, steering	N/A	

		committee, end point adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see item 21a for DMC)		
Introduction Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Chronic musculoskeletal pain (CMSP) severely affects the individual's quality of life, functioning and ability to work, and comes with significant societal costs for sick leave and loss of productivity. After completing an Interdisciplinary Pain Rehabilitation Program (IPRP), patients with CMSP experience a gap in the return to work (RTW) process when the responsibility for RTW is taken over by the employer. The employers have a crucial role in a successful RTW process but may lack knowledge regarding the condition and how to support the employee with CMSP in the best way during RTW. Barriers for RTW for persons with CMSP are for example lack of support at the workplace, not finding the right fit between the employee's physical abilities and work tasks, or problems with relationships with supervisors or coworkers. Key factors for a successful RTW are communication and collaboration between the employer and the employee. To facilitate the important interaction between employer and employee a shared smartphone application may be a tool for increasing a successful outcome in the RTW process. Smart phone applications as digital support has shown promising results for persons with chronic pain and can be helpful especially in an out-clinic setting. They are easily accessed, can enable management of the condition, and reduce pain interference. Focusing on self-management and empowerment are important parts of successful digital support. Self-monitoring can contribute to learning about consequences of actions and behaviours in daily life. Understanding and using own self-monitoring data for making changes in daily activities can give a sense of control and	Page 5-6, manuscript file

			motivation for continued use of self-management strategies. Although positive effects of digital support have been shown there are limitations related to low overall quality of smartphone apps for CMSP and lack of rigorous assessment of their effectiveness.	
Objectives	7	Specific objectives or hyptheses	The aim is to evaluate the clinical effectiveness of a digital support (SWEPPE) for promoting a sustainable RTW for persons with CMSP and to facilitate the employers' supportive role and responsibilities in the process. The hypothesis is that using SWEPPE will decrease the need for sick leave.	Page 7, manuscript file
Trial design	8	Description of trial design, including type of trial	Registry-based randomized controlled trial with parallel groups.	Page 7, manuscript file
Methods Study setting	9	Description of study settings (e.g., community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Specialist and primary care level health care in Sweden reporting to the Swedish National Quality Registry for Pain Rehabilitation (SQRP). Study cites are listed in the protocol (ClinicalTrials.gov registration number NCT05058547)	Page 7, manuscript file
Eligibility criteria	10	Inclusion and exclusion criteria for participants.	Inclusion Criteria: Patients entering the trial must have completed an Interdisciplinary Pain Rehabilitation Program (IPRP). The principal inclusion criteria for IPRP in Sweden are: • persistent or intermittent pain lasting ≥3 months • pain affecting daily activities to a large extent, • completed systematic assessment and non-pharmacological optimization is completed, • screening for psychosocial risk factors and differential diagnosis completed	Page 8, manuscript file

			In addition, the following criteria will be applied: • Age 18-65 years • Completed participation in IPRP at any of the participating units. • Having an employment to return to after IPRP or having returned to work but need continued support for creating a sustainable work situation after IPRP. Exclusion criteria: • Completed IPRP but are unemployed or unable to return to work.	
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	SWEPPE, a smartphone application where the individual can create an action plan, perform daily registrations of health aspects, self-monitoring of health aspects and goals, have access to a library with evidence-based facts and a coach, and possibility to share information with the employer. The participants will use SWEPPE for 12 months. Participants randomized to the control group will not receive any active intervention for RTW after IPRP.	Page 9-10, manuscript file
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (e.g., drug dose change in response to harms, participant request, or improving/worsening disease)	N/A	
	11c	Strategies to improve adherence to intervention	N/A	

		protocols, and any procedures for monitoring adherence (e.g., drug tablet return, laboratory tests)		
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	The participants can initiate and seek other types of health care or support during their RTW process based on their needs.	Page 10, manuscript file
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (e.g., systolic blood pressure), analysis metric (e.g., change from baseline, final value, time to event), method of aggregation (e.g., median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Outcome assessments in the present trial are intended to capture the complexity of pain based on the biopsychosocial model namely medical, psychological, and social (total life situation) factors impacting on the work situation. It has been recommended to include multiple outcomes in clinical trials for persons with CMSP to capture important domains affected by symptoms such as functioning and health-related quality of life. The primary and secondary outcomes are collected for evaluation of the clinical effectiveness of SWEPPE, and the complementary variables will be collected based on their effect on the outcome.	Page 12-16, manuscript file
Participant timeline	13	Time schedule of enrollment,	Figure 1.	Page 7, figure 1

		interventions (including any runins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (Figure).		
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Since there is no established minimal clinical important difference regarding sick leave, the sample size calculation was inspired by previous research regarding patterns of sick leave after IPRP [45,46]. It has been shown that the distribution of sick leave change over time from full-time to partial sick leave after IPRP [45] and sick leave are reduced with approximately 16 net days from one year before to two years after IPRP. [46] Therefore, an estimated difference between the groups of 20 net days with a standard deviation of 60 and an effect-size of 0.333 was set for rejection of the null hypothesis. To detect this difference with a power of 80% and a significance level of 0.05 a total sample size of 300 participants (150/group) are needed. With an allowance for 20% of participants lost to follow-up we aim to recruit a total sample size of 360 participants (n=180 intervention, n=180 control).	Page 11, manuscript file
Recruitment	15	Strategies for achieving adequate participant enrollment to reach target sample size	Participants will be recruited from multiple special and primary care level health care providing IPRP for patients with chronic pain.	Page 8-9, manuscript file
Assignment of interventions Allocation sequence generation	16a	Method of generating the allocation sequence (e.g., computer-generated random numbers), and list of	As sick leave history is a strong predictor for future sick leave (47) participants will be stratified based on self-reported number of sick leave days during the year before IPRP. Participants will be divided in high (total number of gross sick leave days ≥ 70) or low sick leave absence and then randomized to intervention or control group. Allocation of the participants to intervention or control group will be	Page 10, manuscript file

		any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (e.g., blocking) should be provided in a separate document that is unavailable to those who enroll participants or assign interventions.	conducted using a block randomization design with varying block sizes of 2-6 (48-50). The allocation sequence will be computer generated and sealed sequentially numbered opaque sealed envelopes will be prepared by one of the researchers (GL).	
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (e.g., central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Sealed sequentially numbered opaque envelopes will be used for implementing the allocation sequence at each participating unit.	Page 10, manuscript file
Implementation	16c	Who will generate the allocation sequence, who will enroll participants, and who will assign participants to interventions	The allocation sequence will be generated by a statistician and one of the researchers (GL) will prepare sequentially numbered opaque sealed envelopes. Enrollment and assignment of participants will be performed by one of the researchers (CT) not involved in preparing the allocation sequence or the envelopes.	Page 10, manuscript file

Blinding	17a	Who will be blinded after assignment to interventions (e.g., trial participants, care providers, outcome assessors, data analysts), and how	Due to the nature of the intervention the participants will not be blinded to group allocation. As randomization to intervention or control group is performed at the completion of IPRP the participants will not have further contact with the health care staff responsible for IPRP or other patients. The participants will be instructed not to reveal their group allocation to the health care staff responsible for IPRP or other patients if they would have further contact.	Page 11, manuscript file
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A	
Data collection, management, and analysis Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (e.g., duplicate measurements, training of assessors) and a description of study instruments (e.g., questionnaires, laboratory tests) along with their reliability and	Data collection for the present trial will start when the IPRP is completed (baseline) and at 12 months follow-up (study ending). Data will be collected from the Swedish Social Insurance Agency's SSIA, the SQRP for specialist and primary care level, supplementary questionnaires to the SQRP, and data registered in SWEPPE (table 1).	Page 16, manuscript file

		validity, if known. Reference to where data collection forms can be found, if not in the protocol.		
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	Data collection for the SQRP is routinely performed when the IPRP is completed and at 12 months follow-up at both primary and specialized care units in Sweden providing IPRP. The supplementary questionnaires will be added to these routine data collections for the SQRP.	Page 16, manuscript file
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (e.g., double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol.	A data management plan (DMP) will be developed by the principal investigator and co-workers and will include a description of research data, information about documentation and quality control of research data, storage and back-up copying of research data, legal and ethical aspects, accessibility and long-term preservation of research data, and responsibility and resources related to the research data.	Page 17, manuscript file
Statistical methods	20a	Statistical methods for analyzing primary and secondary outcomes. Reference to where	A statistical analysis plan will be developed with details of statistical analyses, handling of missing data and other possible analyses for example subgroups. Descriptive statistical analyses will be performed for transparent reporting of participant characteristics. The clinical effectiveness off SWEPPE will be analysed using	Page 17-18, manuscript file

		other details of the statistical analysis plan can be found, if not in the protocol.	effect-size and uni- and multivariate statistical analyses as a preliminary plan. Data from SWEPPE will be analysed using repeated measures analyses. All p-values will be presented and a p-value of <0.05 will be considered significant.	
	20b	Methods for any additional analyses (e.g., subgroup and adjusted analyses)	A statistical analysis plan will be developed with details of statistical analyses, handling of missing data and any additional analyses, for example subgroup and adjusted analyses.	Page 17-18, manuscript file
	20c	Definition of analysis population relating to protocol nonadherence (e.g., as-randomized analysis), and any statistical methods to handle missing data (e.g., multiple imputation)	Data from primary and secondary outcomes will be analysed according to intention-to-treat.	Page 17-18, manuscript file
Data monitoring	21a	Composition of DMC; summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed.	All data in the trial will be monitored regularly. Since no sponsors or competing interests exists, monitoring of data will be performed independently. To ensure proper handling and storing of data (structure, organization, file naming), the DMP will be reviewed regularly by the principal investigator and co-workers.	Page 17, manuscript file

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A	
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	SWEPPE can be assumed not to create adverse events and is considered a safe intervention. Nevertheless, all participants will be encouraged to report any adverse events or unintended effects of trial intervention or trial conduct such as unexpected side effects or deterioration of symptoms.	Page 18, manuscript file
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	To facilitate adherence to the study protocol the project coordinator (CT) will have regular contact (every second week) with the participating units during the study period. Processes to be reviewed are participant screening and eligibility. Documentation of the recruitment and randomization/allocation process, for example eligible patients asked to participate, the number of patients included, excluded or declining participation, performed by CT will be reviewed by the researchers (GL, MB).	Page 18, manuscript file
Ethics and dissemination Research ethics approval	24	Plans for seeking REC/IRB approval	The study is approved by the Swedish Ethics Review Board (Dnr 2020-01593, Dnr 2021-01854).	Page 18-19, manuscript file

Protocol amendments	25	Plans for communicating important protocol modifications (e.g., changes to eligibility criteria, outcomes, analyses) to relevant parties (e.g., investigators, RECs/IRBs, trial participants, trial registries, journals, regulators)	Any important modifications of the study protocol will be communicated to the Swedish Ethics Review Board and to the participants	Page 18-19, manuscript file
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorized surrogates, and how (see item 32)	Informed consent will be collected from all participants by one of the researchers (CT). See also the model consent form in S3.	Page 18, manuscript file.
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A	
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect	Confidentiality will be protected by coding of individual participants' collected data.	Page 18-19, manuscript file

		confidentiality before, during, and after the trial		
Declaration of interest	28	Financial and other competing interests for principal investigators for the overall trial and each study site	The authors have no competing interests to declare.	Page 19, manuscript file
Access to data	29	Statement of who will have access to the final trial data set, and disclosure of contractual agreements that limit such access for investigators	Data will be stored at a password protected project server at Linköping University and will not be accessed by unauthorized persons.	Page 19, manuscript file
Ancillary and post-treatment care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A	
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, health care professionals, the public, and other relevant groups (e.g., via publication, reporting in results	The study results will be submitted to peer-review journals for publication and will be presented in national and international research networks, clinical settings, and patient associations.	Page 19, manuscript file

		databases, or other data-sharing arrangements), including any publication restrictions		
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A	
	31c	Plans, if any, for granting public access to the full protocol, participant-level data set, and statistical code	The study protocol is available via Clinicaltrial.gov. There is no present plan regarding public access of participant-level data set or statistical code.	Page 18-19, manuscript file
Appendices Informed consent material	32	Model consent form and other related documentation given to participants and authorized surrogates	The consent form is design based on the Swedish Ethics Review Board recommendation and includes written information about the study, supplementary file S3.	Page 18, manuscript file and page 21 in supplemental file
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A	